WW 1652 Box-seg



Apple o.

10/004,115

Confirmation No.:

3895

**Applicant** 

ASAKO et al.

Filed:

December 6, 2001

TC/A.U.

1652

Examiner

Elizabeth Slobodyansky

Docket No.

7372/72249

Customer No.:

22242

February 25, 2004

## ACCOMPANYING STATEMENT TO SUPPORT FILING AND SUBMISSION OF CORRECTED SEQUENCE LISTING IN ACCORDANCE WITH 37 C.F.R. §§ 1.821-1.825

U.S. Patent and Trademark Office 2011 South Clark Place Customer Window, Mail Stop <u>Sequence</u> Crystal Plaza Two, Lobby, Room 1B03 Arlington, VA 22202

## Dear Sir:

In connection with the corrected Sequence Listing submitted concurrently herewith, the undersigned hereby states the following:

1. A Sequence Listing (paper) was submitted with the instant application on December 6, 2001 and with the July 30, 2002 submission. Included in the Sequence was the amino acid (SEQ ID NO:34) and DNA (SEQ ID NO:35) sequences of a protein produced by *Corynebacterium pseudodiphtheriticum*.

The cDNA encoding the protein was originally cloned into the plasmid pWAR2 as described in *Appl. Microbiol. Bitechol.* (1999) 52:386-392, by Dr. Nobuya Itoh, one of the listed

1

Ì

inventors on the instant application. The cDNA encoding the protein was subcloned from pWAR2 into pUAR. On November 27, 2000, pUAR was deposited in an approved depository facility and assigned deposit number FERM P-18127, later renamed as FERM BP-7752. Copies of the deposit certificates, and translations, are enclosed herewith.

During November and December 2000, the nucleotide sequence of the cDNA was determined from pUAR. This sequence was included in the instant application.

On December 7, 2000, Japanese application 2000-372704; on January 15, 2001 Japanese application 2001-006144 was filed; on February 2, 2001 Japanese application 2001-026594 was fled; and on June 11, 2001, Japanese application 2001-175175 was filed. On December 6, 2001, the instant application was filed, claiming priority from the above-identified Japanese applications.

In January 2003, the protein encoded by the cDNA contain in pUAR was produced, purified and subjected to mass analysis with TOF-MS. The analysis showed the molecular weight of the protein to be 36,232.03. However, the molecular weight calculated from the amino acid sequence shown in SEQ ID NO:34 and/or SEQ ID NO:35 suggest the protein should have a molecular weight of 40,344.30. Due to the difference in molecular weight, Applicants resequenced the deposited pUAR cDNA and found three errors in the nucleic acid sequence. Included herewith is a marked up copy of the SEQ ID NO:34 and SEQ ID NO:35.

In view of the errors, Applicants include herewith a corrected Sequence Listing, in paper copy and computer readable form copy, and request entry of the same in the instant application. As stated in MPEP §2163(I)(B) (Rev. 1, Feb. 2003):

With respect to the correction of sequencing errors in applications disclosing nucleic acid/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. See, e.g., Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 Genome Research 251-59 (1998). If an application as filed includes sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR 1.801 et seq., amendment may be permissible. Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed. Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error. Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR 1.804 stating that the biological material which is deposited is a biological material specifically defined in the application as filed.

Applicants note that a sample of the biological material containing the cDNA from which the original and corrected version of SEQ ID NOs:34 and 35 were determined (pUAR) was submitted to an approved depository agency prior to the earliest priority date of the instant application. Applicants assert that one of skill in the art, upon finding a discrepancy between the predicted and calculated molecular weight of the polypeptide, would have re-sequenced the cDNA encoding the polypeptide and identified the error, as Applicants have now done.

As the errors in the sequence are minor, and as the cDNA was submitted to an approved depository agency priority to the filing of the instant application and the priority applications, Applicants respectfully request entry of the enclosed corrected Sequence Listing in place of the Sequence Listing previously submitted in this application.

- 2. The present submission does not include any new matter.
- 3. On information and belief, based on the declaration appended hereto, the content of the 23 page Sequence Listing being filed herewith, and the attached computer readable copy of

Statement to Support Filing U.S. Appln. No. 10/004,115

the Sequence Listing, submitted in accordance with 37 C.F.R. §1.821(c) and (e), and 37 C.F.R. §1.825(b), respectively, are identical; and

4. All statements made herein of my own knowledge are true and that all statements made on information and belief are believe to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by find or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Applicants respectfully request entry of the Sequence Listing into the application.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Kendrew H. Colton Reg. No. 30,368

Fitch, Even, Tabin & Flannery 1801 K Street, N.W. Suite 401L Washington, D.C. 20006-1201 Telephone No. (202) 419-7000 Facsimile No. (202) 419-7007

Attachments:

Declaration and

- 1) Corrected Sequence Listing
- 2) Computer readable copy of corrected Sequence Listing
- 3) Mark-up of Sequence Listing as originally filed
- 4) Copies of deposit certificate FERM P-18127 (FERM BP-7752)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No: 7372-72249

In re patent application of

ASAKO, HIROYUKI et al.

Serial No. 10/004,115

Filed: December 6, 2001

For: PROCESS FOR PRODUCING OPTICALLY ACTIVE 4-HALO-3-HYDROXYBUTANOATE

## STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE WITH 37 C.F.R. §§ 1.821-1.825

Assistant Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Mail Stop SEQUENCE

Sir:

In connection with a Sequence Listing submitted concurrently herewith, the undersigned hereby states that:

- 1. the submission, filed herewith in accordance with 37 C.F.R. § 1.821(g), does not include new matter;
- 2. the content of the attached paper copy and the attached computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same.

Respectfully submitted,

Date

James A. Coburn

HARBOR CONSULTING IP SERVICES, INC. 1500A Lafayette Road, #262 Portsmouth, N.H. 800-318-3021